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(54) **ADJUSTABLE CUTTING GUIDE APPARATUS FOR USE IN ORTHOPEDIC SURGERY**

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A61B 17/15 (2006.01)
A61B 17/00 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/15*** (2013.01); ***A61B 17/155*** (2013.01); *A61B 2017/0023* (2013.01); *A61B 2017/00477* (2013.01)

(58) **Field of Classification Search**
CPC A61B 17/15; A61B 17/154; A61B 17/155
See application file for complete search history.

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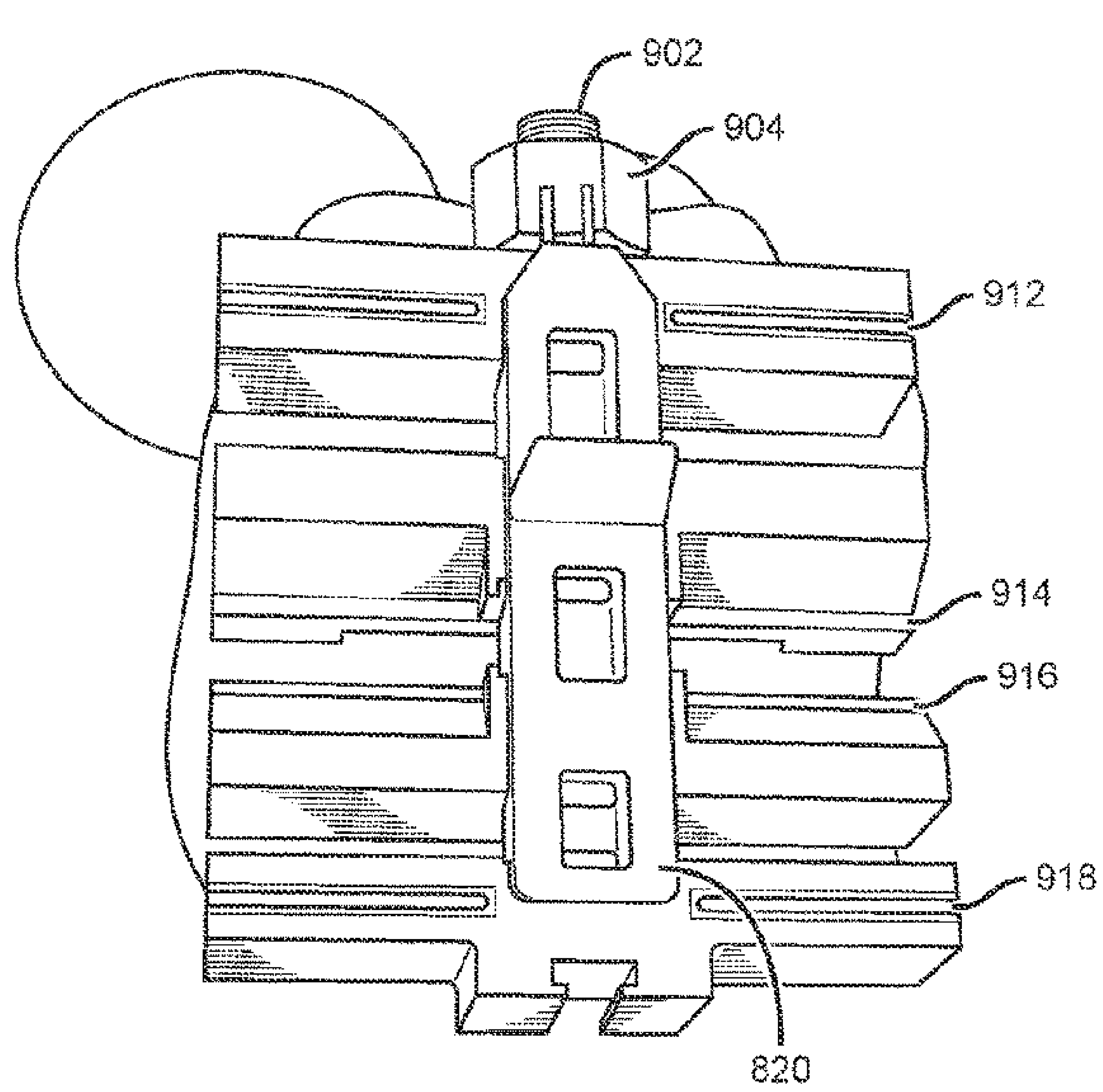
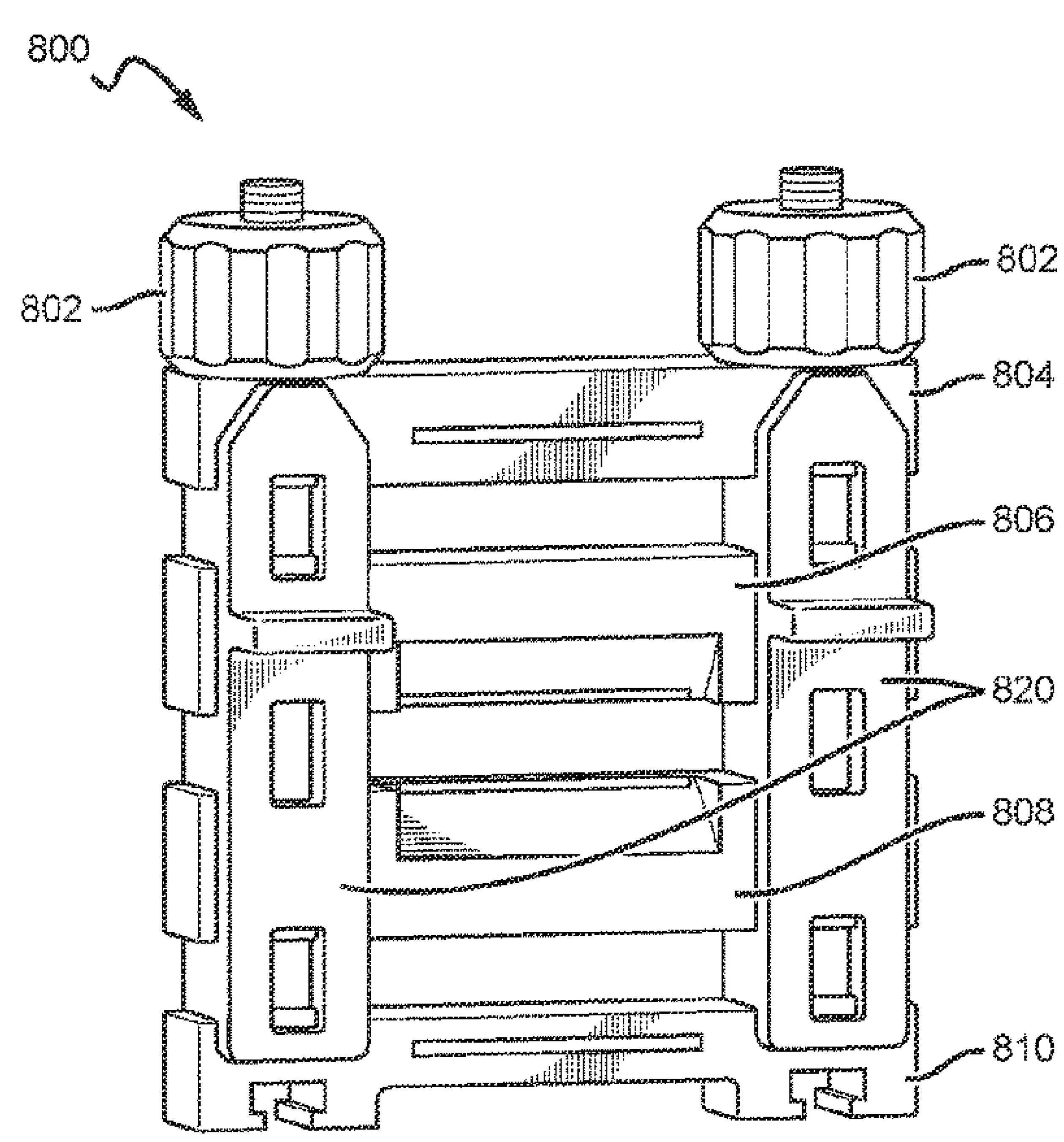
(57) **ABSTRACT**

Cutting guides for use in orthopedic surgery are disclosed. In some embodiments, the cutting guides comprise monolithic polymer cutting blocks with one or more slots and guide inserts to allow for the provision of various desired surgical cuts to a bone by a cutting saw. In other embodiments, the cutting guides may comprise adjustable guide bars with one or more slots and inserts to allow for various desired surgical cuts to a bone. The location and directionality of the cuts may be configured to match the geometry of a surgical implant.

14 Claims, 6 Drawing Sheets





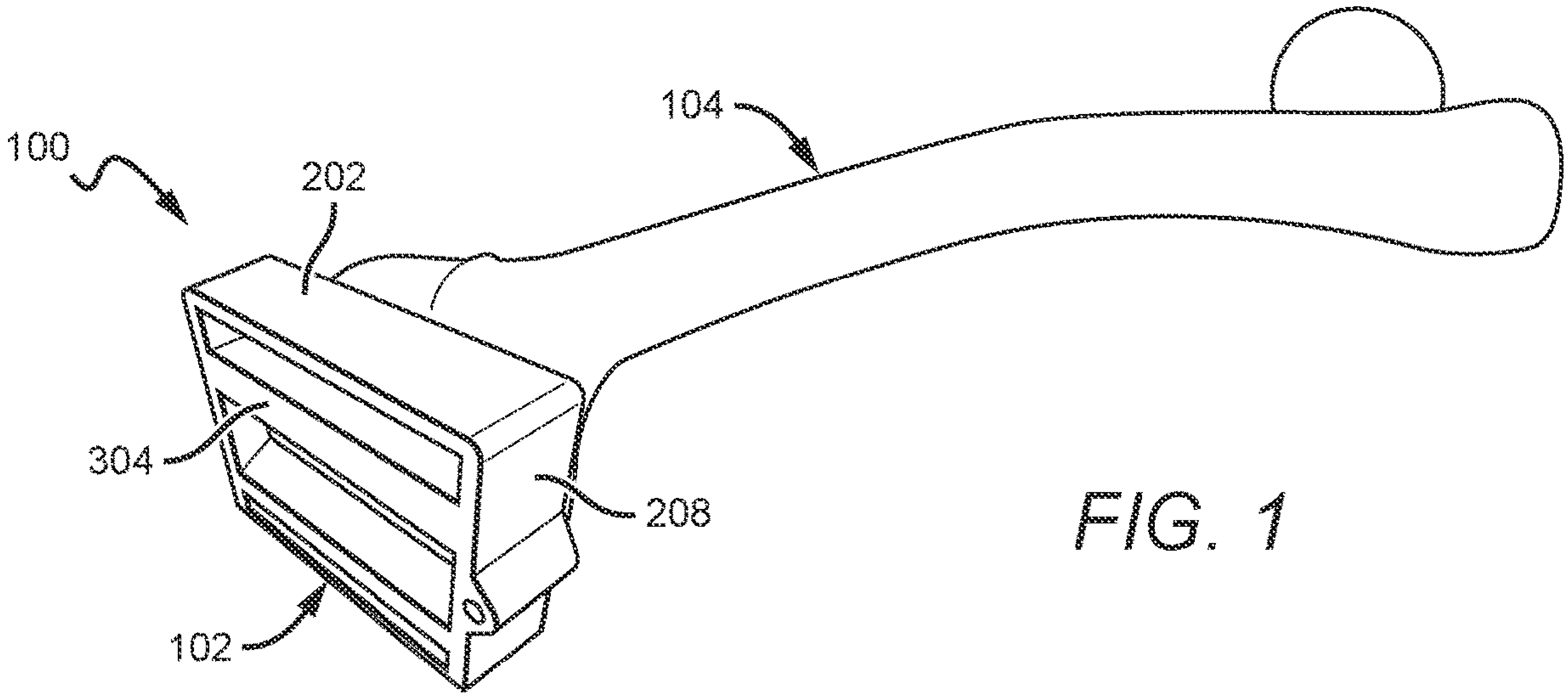
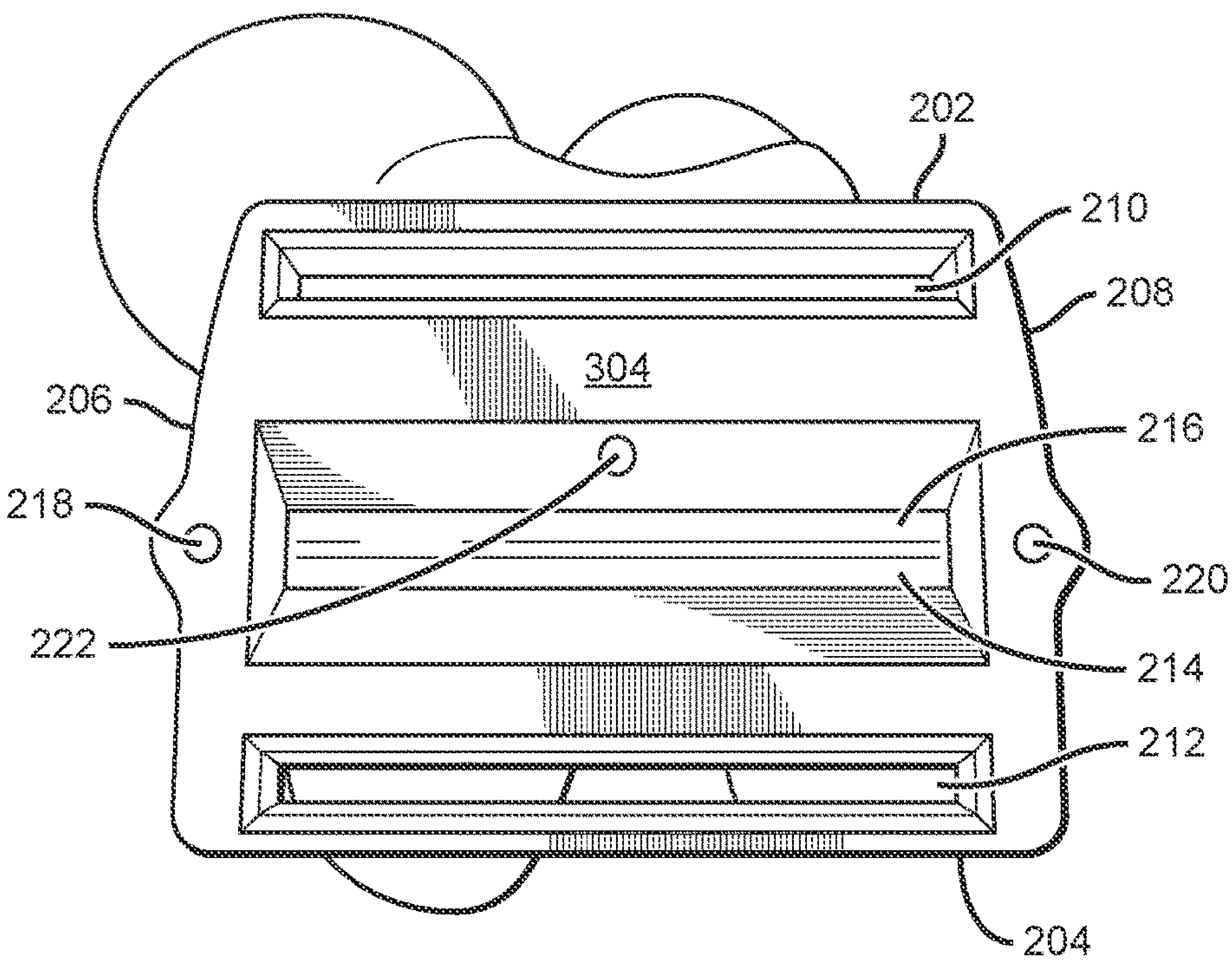

100
104
202
304
208
102

FIG. 1


202
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206
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218
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212
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FIG. 2

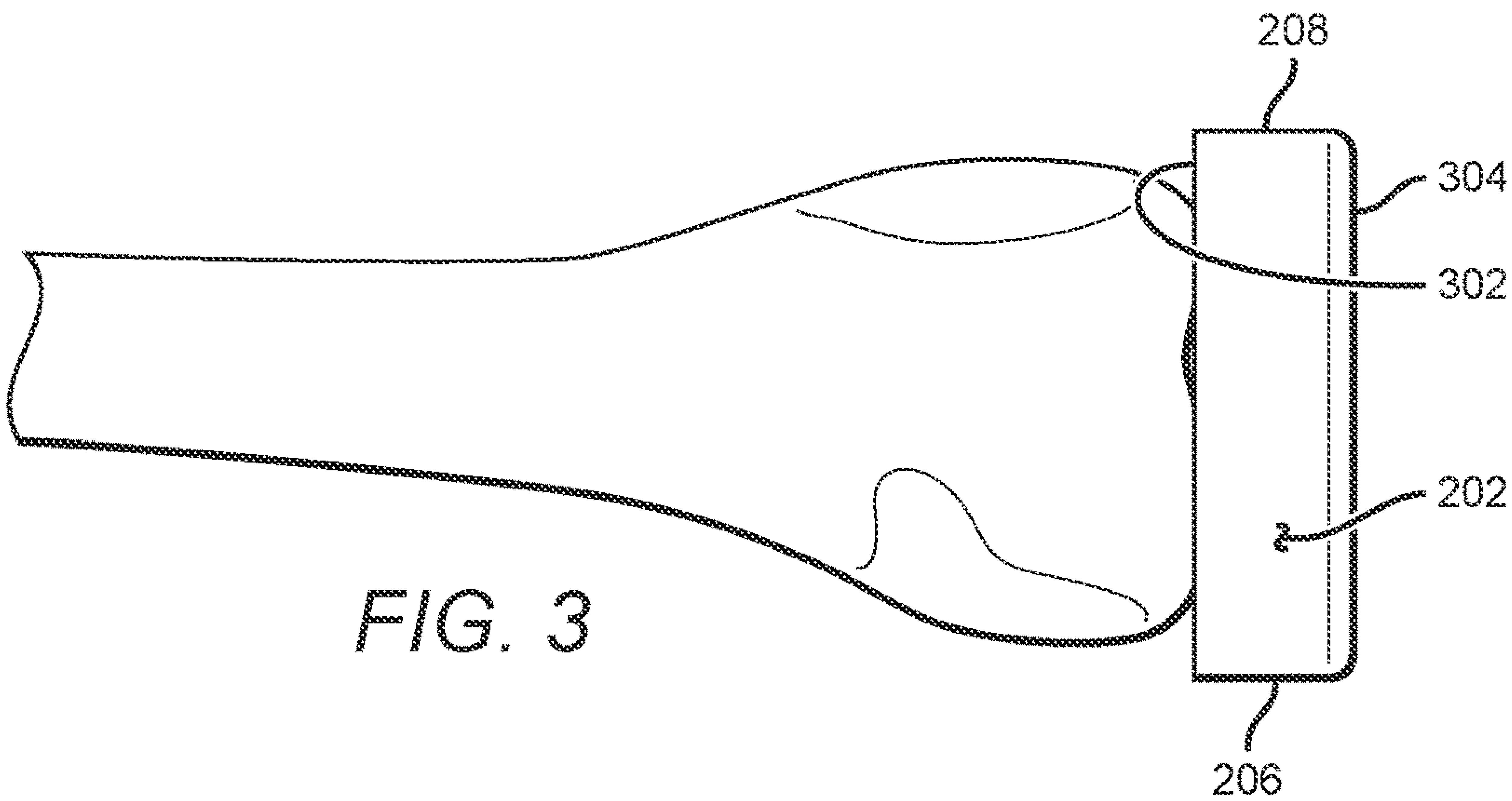

FIG. 3

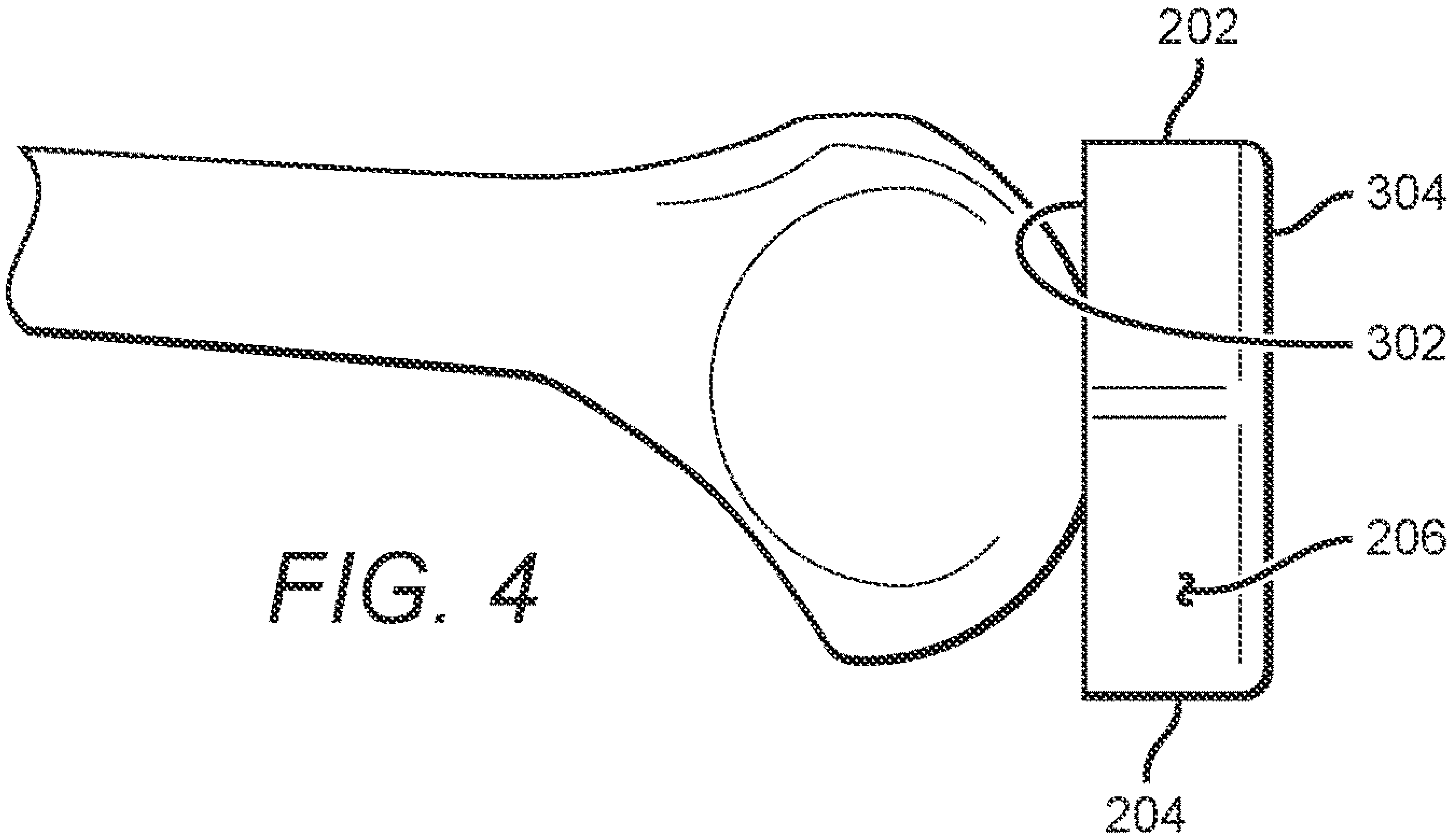

FIG. 4

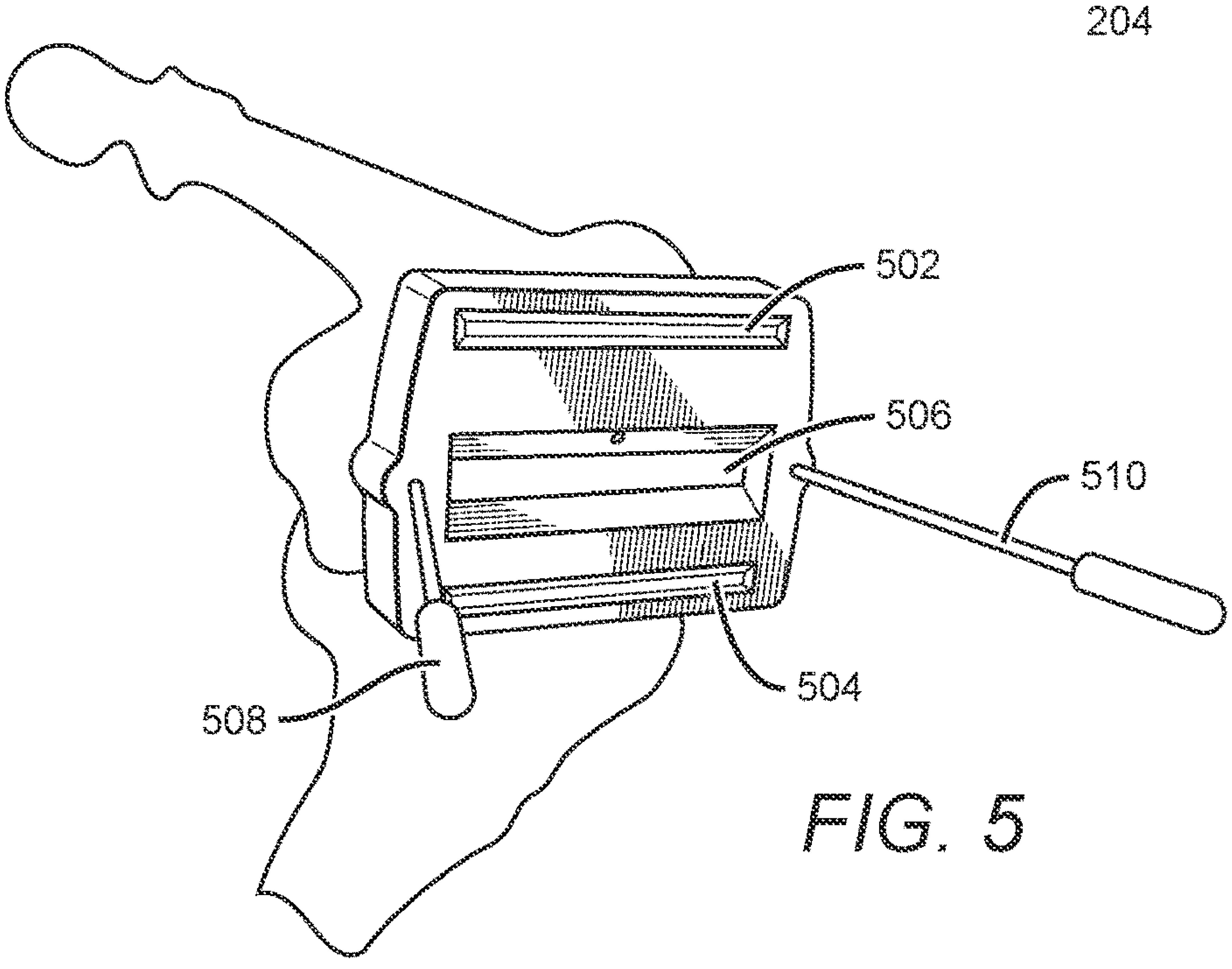

FIG. 5

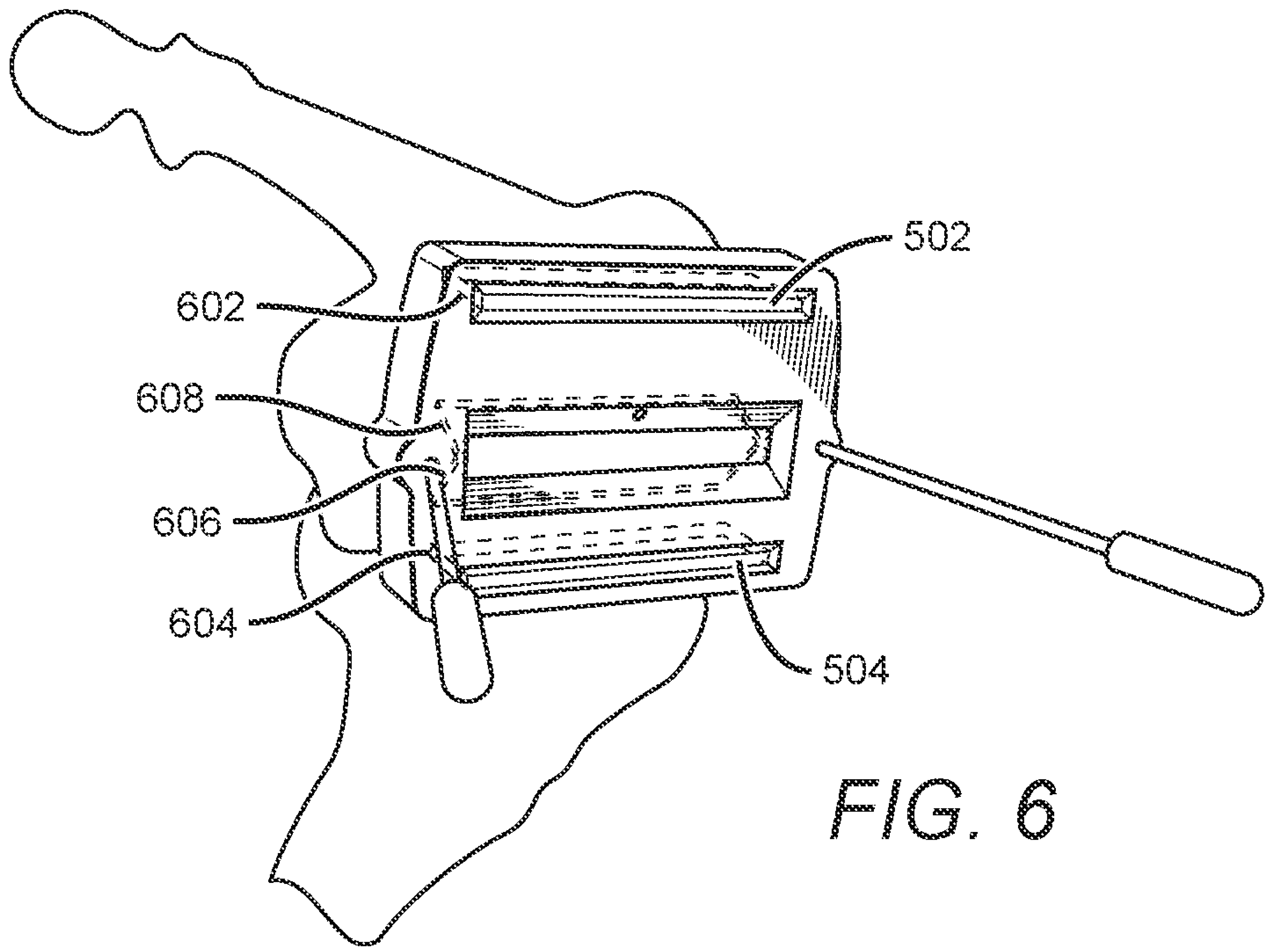

FIG. 6

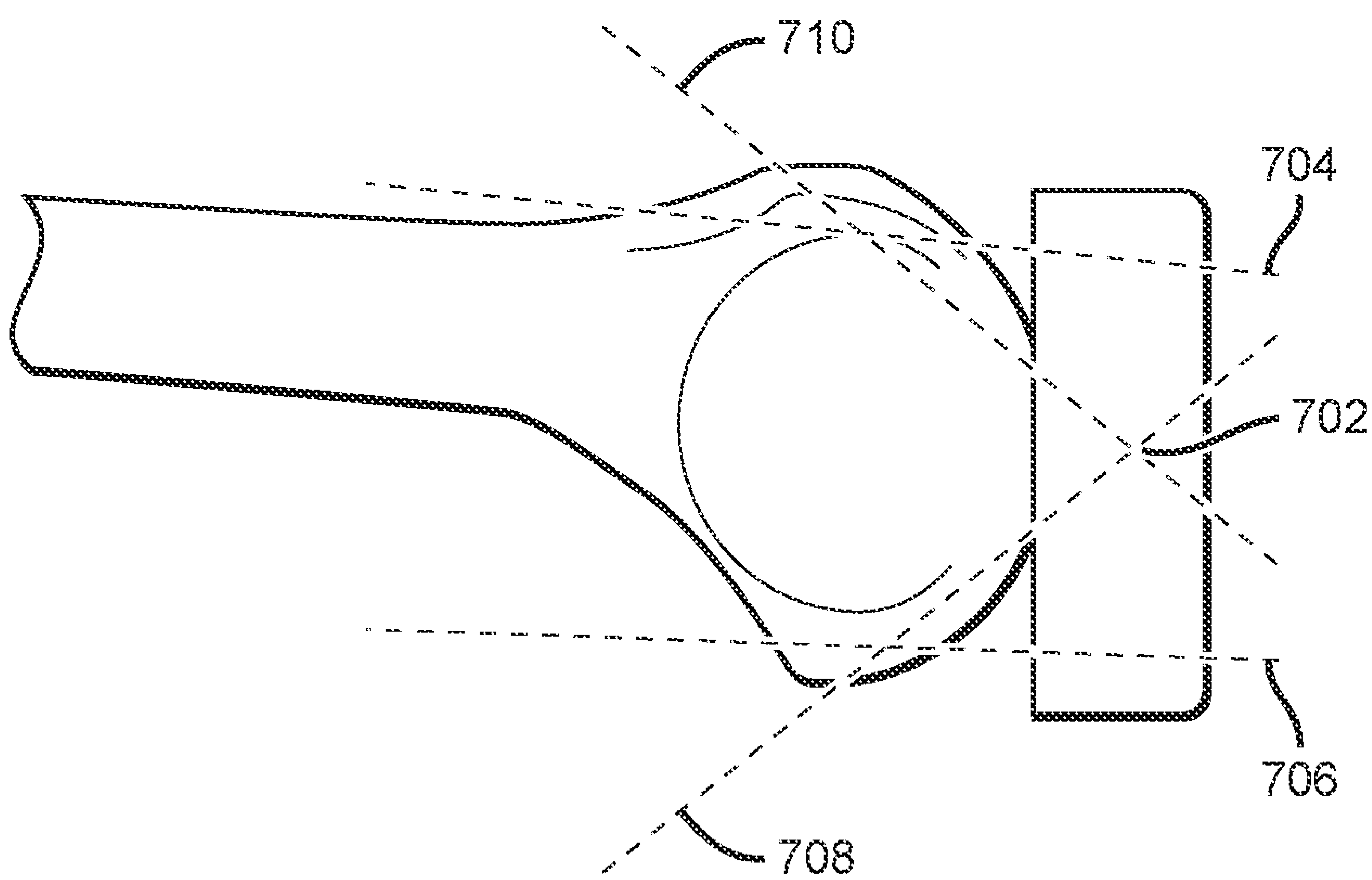

FIG. 7

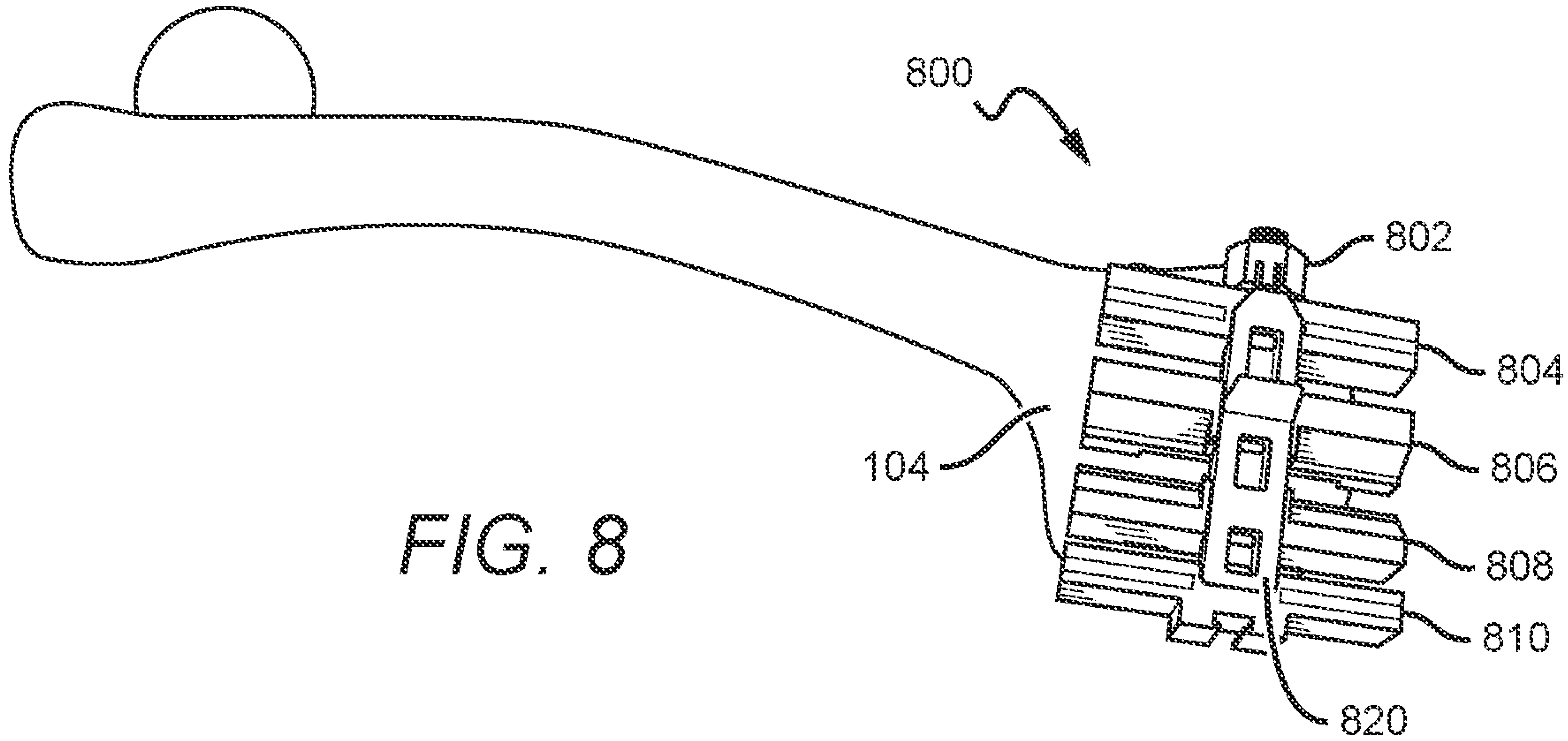

FIG. 8

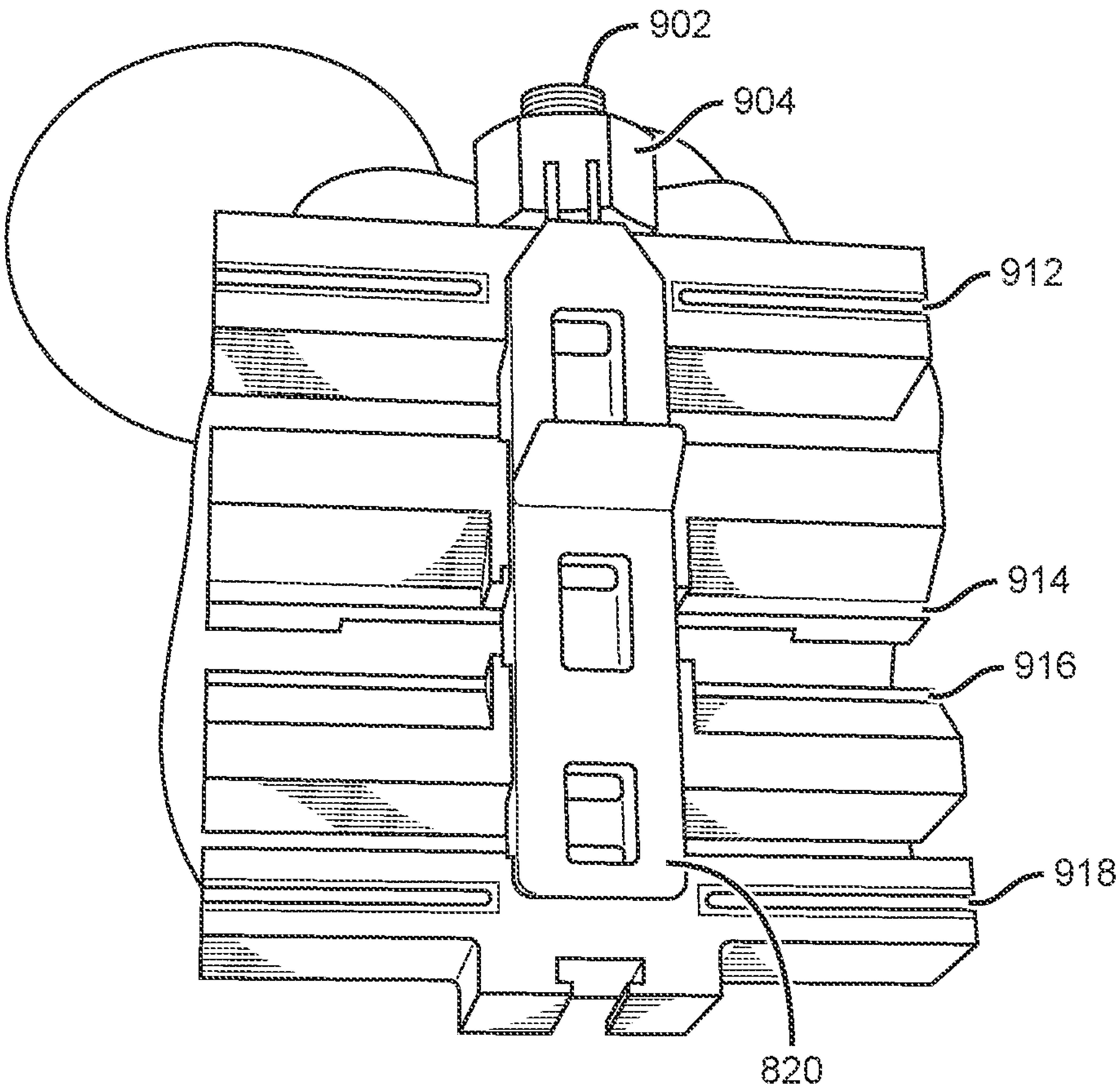

FIG. 9

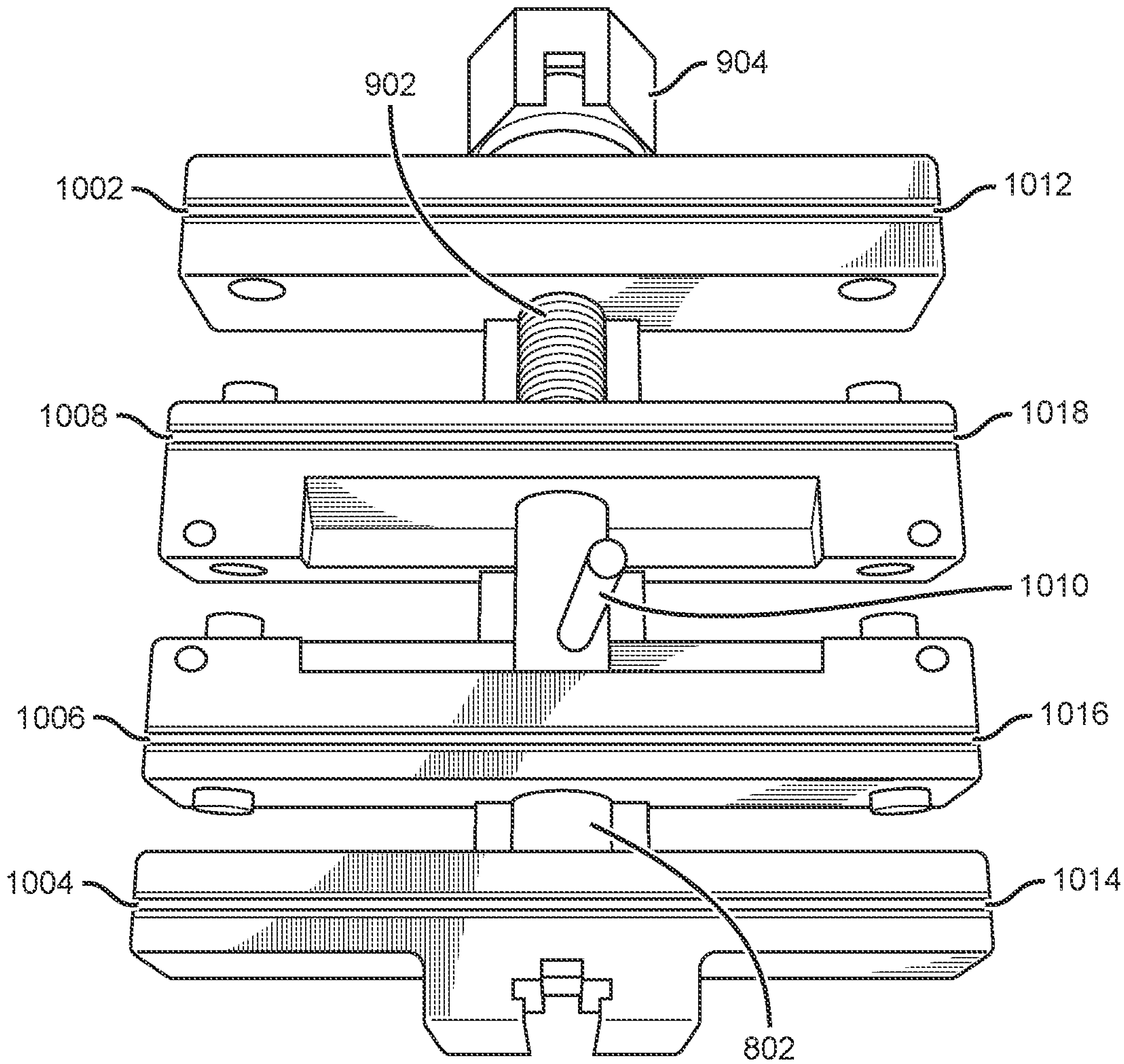

FIG. 10

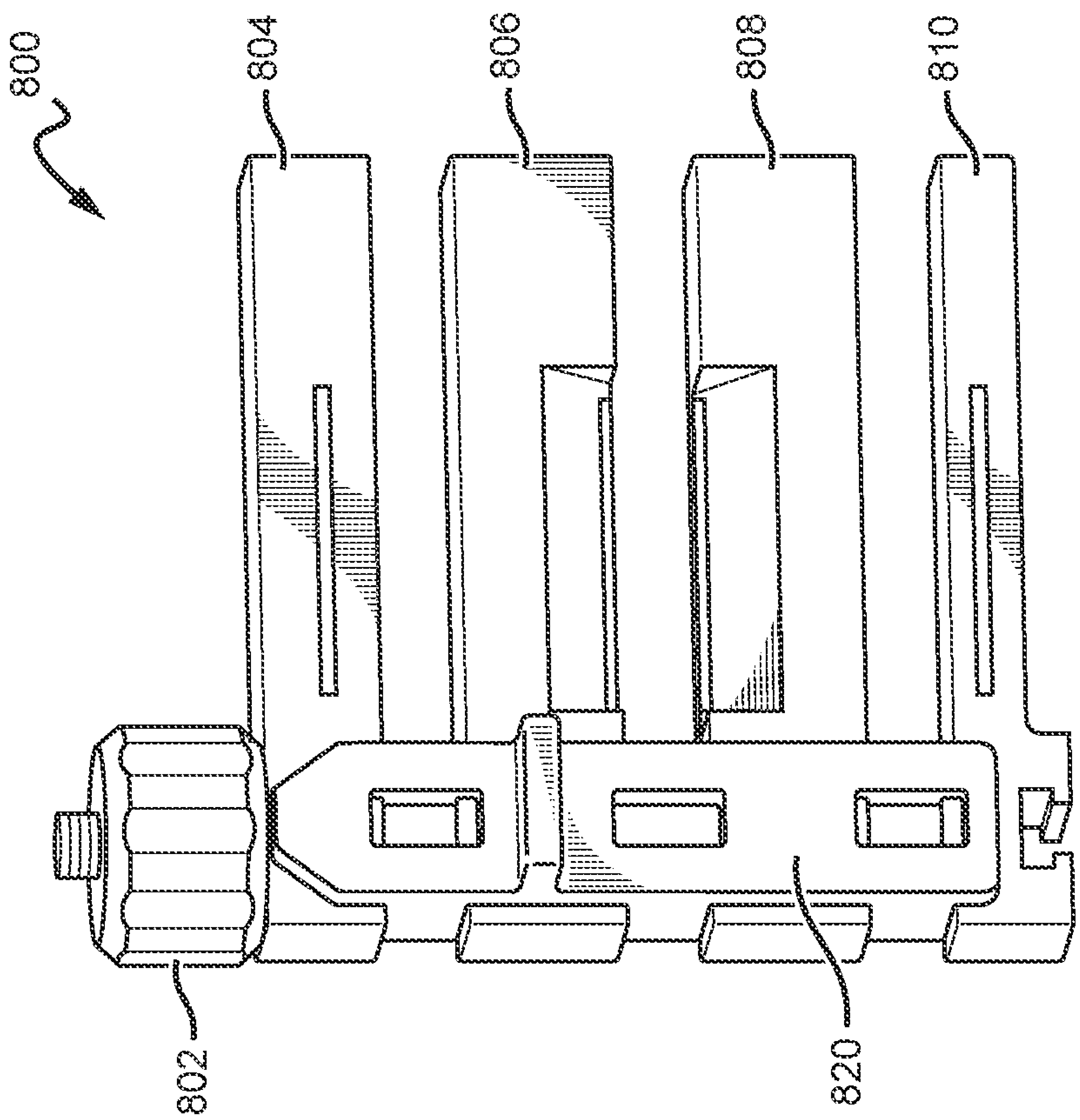

FIG. 12

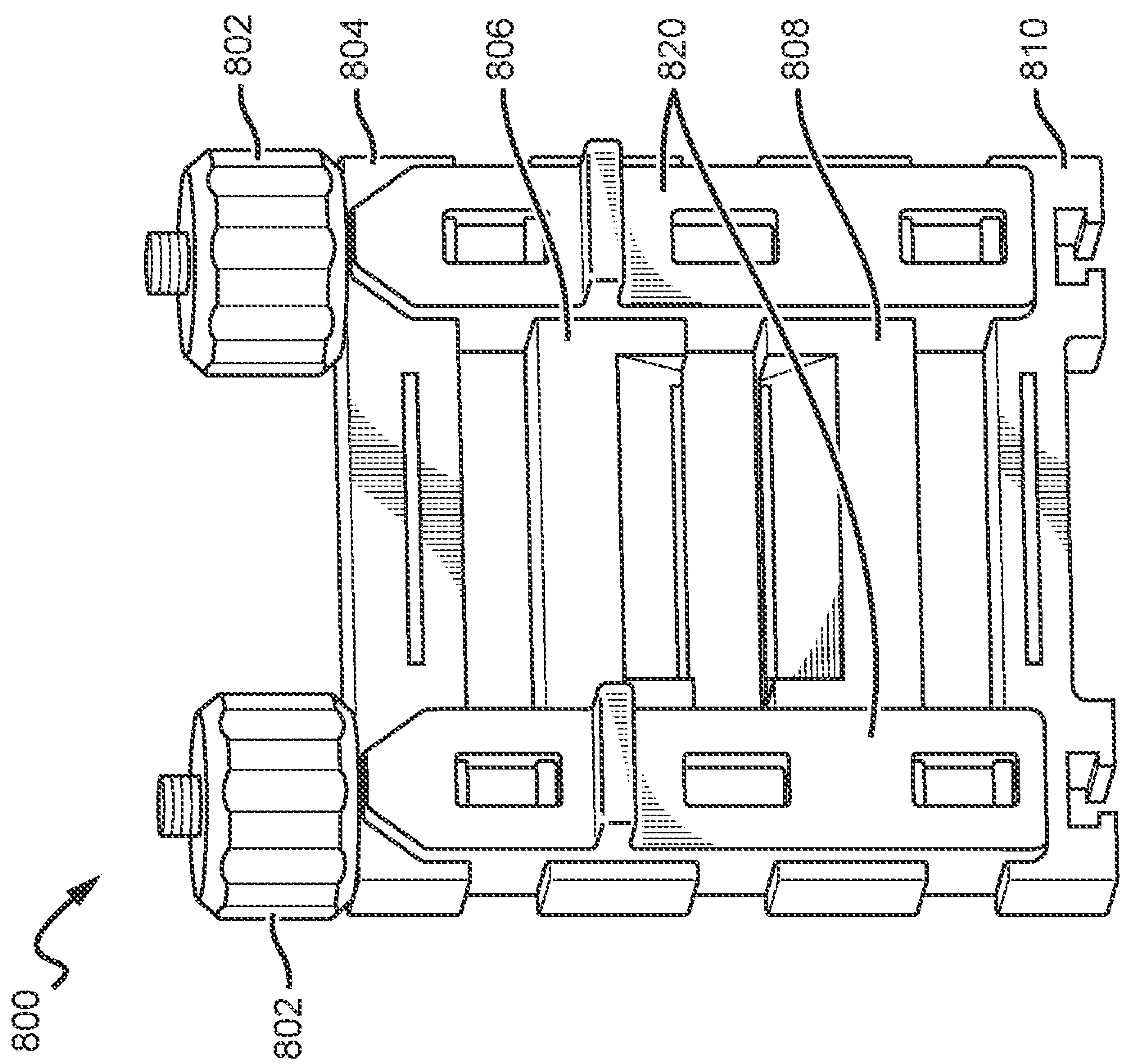

FIG. 11

ADJUSTABLE CUTTING GUIDE APPARATUS FOR USE IN ORTHOPEDIC SURGERY

BACKGROUND OF THE DISCLOSURE

Field of the Disclosure

The present disclosure relates to medical devices, in particular, cutting guides for use in orthopedic surgical procedures, including but not limited to, knee arthroplasty, ankle arthroplasty, wrist arthroplasty, shoulder arthroplasty, and osteotomy.

Description of the Related Art

Knee arthroplasty, or total knee replacement, is a surgical procedure to resurface a knee joint with severe damage. During a knee arthroplasty procedure, a surgeon will resurface a patient's distal femur, proximal tibia, and/or patella so that an artificial knee prosthesis can be fitted to the patient's knee. The femoral component of the prosthesis generally has a smooth outer curvature configured to interface with the tibial component of the prosthesis and a plurality of interior planar surfaces configured to interface with the surgically prepared distal femoral surface. The surgeon will form a plurality of cuts to the patient's distal femur using a surgical cutting instrument, such as a sagittal saw, in order to prepare the distal femur to receive the femoral component of the prosthesis. One concern during the procedure is ensuring the precise location of each of these cuts to the distal femur, so typically the surgeon will use a cutting guide for precision.

Traditional cutting guides known throughout the art are normally made from large metal pieces for stability and sturdiness to minimize the wear and tear caused by recurrent surgical procedures. For example, U.S. Pat. No. 8,052,692 discloses a cutting guide for use in knee arthroplasty, touting the cutting guide's stability and structural continuity provided by "more mass of material" and criticizing other designs with less metal as less stable and more likely to break during operation.

Although a metallic cutting guide may have been an attractive option for stability reasons, it increases the cost of manufacturing the cutting guide and necessitates its reuse for numerous procedures over a long period of time. The high expense is disadvantageous because it limits the number of cutting guides available in house to surgeons. Additionally, a reusable cutting guide must be sterilized before each use, which can take up to 5-6 hours, and must be recalibrated periodically, which further affects the time and cost associated with maintaining a reusable cutting guide. Therefore, in hospitals and offices that are only able to afford to keep one cutting guide in house, a surgeon will have to wait to perform subsequent procedures until the cutting guide has been sterilized and/or recalibrated, greatly limiting the number of procedures that can be performed in one day. In contrast, a cost-effective, single use cutting guide requires no sterilization process or recalibration because it will be disposed of after each use, presenting virtually no limitations on how many procedures a surgeon could perform in a single day.

Thus, there is a need for a single use cutting guide with a low enough cost of manufacturing as to justify disposing of the cutting guide after a single procedure and purchasing a new cutting guide for each subsequent procedure. The single use cutting guide must also be sufficiently durable and reliable to allow the surgeon to perform a successful procedure. The present disclosure includes such a device that is

lower in cost than traditional cutting guides but remains sufficiently reliable for successful procedures.

SUMMARY OF THE DISCLOSURE

The present disclosure includes single use cutting guides to be used in various orthopedic surgical procedures such as knee arthroplasty, ankle arthroplasty, and wrist arthroplasty. In some embodiments, the cutting guide comprises a polymer substrate cutting block and metal guide inserts that are insert molded into the cutting block. It is understood that other assembly methods for the cutting guide are possible such as press-fitting the metal guide inserts into the polymer substrate cutting block, for example. In other embodiments, the cutting guide comprises a plurality of polymer guide bars mounted on a polymer base and metal guide inserts that are insert molded into the guide bars. In certain embodiments, the cutting guide further comprises pins to secure the guide to a patient's bone during a procedure. These and other elements of the present disclosure allow for a cost-effective yet reliable cutting guide that can be successfully used for a single procedure and then discarded.

These and other further features and advantages provided in this disclosure would be apparent to those skilled in the art from the following detailed description, taken together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a cutting block according to one embodiment of the present disclosure;

FIG. **2** is a distal end view of a cutting block according to one embodiment of the present disclosure;

FIG. **3** is an anterior top view of a cutting block according to one embodiment of the present disclosure;

FIG. **4** is a lateral side view of a cutting block according to one embodiment of the present disclosure;

FIG. **5** is a perspective view of a cutting guide apparatus comprising a cutting block, guide inserts, and pins according to one embodiment of the present disclosure;

FIG. **6** is a perspective view of the embodiment shown in FIG. **5** with the internal configuration of the guide inserts shown in broken line;

FIG. **7** is a lateral side view of a cutting guide apparatus according to one embodiment of the present disclosure with cut paths shown in broken line;

FIG. **8** is a perspective view of an adjustable cutting guide apparatus according to one embodiment of the present disclosure;

FIG. **9** is a distal/end view of an adjustable cutting guide apparatus according to one embodiment of the present disclosure.

FIG. **10** is a proximal view of an adjustable cutting guide apparatus according to one embodiment of the present disclosure.

FIG. **11** is a perspective view of a cutting guide apparatus according to one embodiment of the present disclosure.

FIG. **12** is a perspective view of a cutting guide apparatus according to one embodiment of the present disclosure.

DETAILED DESCRIPTION OF THE DISCLOSURE

Throughout this disclosure, the embodiments illustrated should be considered as exemplars, rather than as limitations on the present disclosure. As used herein, the term "invention," "device," "apparatus," "method," "disclosure," "present invention," "present device," "present apparatus," "present method," or "present disclosure" refers to any one of the embodiments of the disclosure described herein, and any equivalents. Furthermore, reference to various features of the "invention," "device," "apparatus," "method," "disclosure," "present invention," "present device," "present apparatus," "present method," or "present disclosure" throughout this document does not mean that all claimed embodiments or methods must include the reference features.

It is also understood that when an element or feature is referred to as being "on" or "adjacent" to another element or feature, it can be directly on or adjacent the other element or feature or intervening elements or features may also be present. In contrast, when an element is referred to as being "directly on" or extending "directly onto" another element, there are no intervening elements present. Additionally, it is understood that when an element is referred to as being "connected" or "coupled" to another element, it can be directly connected or coupled to the other element or intervening elements may be present. In contrast, when an element is referred to as being "directly connected" or "directly coupled" to another element, there are no intervening elements present.

Furthermore, relative terms such as "inner," "outer," "upper," "top," "above," "lower," "bottom," "beneath," "below," and similar terms, may be used herein to describe a relationship of one element to another. Terms such as "higher," "lower," "wider," "narrower," and similar terms, may be used herein to describe angular relationships. It is understood that these terms are intended to encompass different orientations of the elements or system in addition to the orientation depicted in the figures.

Although the terms first, second, third, etc., may be used herein to describe various elements, components, regions, and/or sections, these elements, components, regions, and/or sections should not be limited by these terms. These terms are only used to distinguish one element, component, region, or section from another. Thus, unless expressly stated otherwise, a first element, component, region, or section discussed below could be termed a second element, component, region, or section without departing from the teachings of the present disclosure. As used herein, the term "and/or" includes any and all combinations of one or more of the associated list items.

The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the disclosure. As used herein, the singular forms "a," "an," and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. For example, when the present specification refers to "an" assembly, it is understood that this language encompasses a single assembly or a plurality or array of assemblies. It is further understood that the terms "comprises," "comprising," "includes," and/or "including" when used herein, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof.

Embodiments as described in the present disclosure can be described herein with reference to view illustrations, some of which are schematic in nature. As such, the actual thickness of elements can be different, and variations from the shapes of the some of the illustrations as a result, for example, of manufacturing techniques and/or tolerances are expected. Thus, the elements illustrated in the some of the figures are schematic in nature and their shapes are not intended to illustrate the precise shape of a region and are not intended to limit the scope of the disclosure.

FIGS. **1-4** show one embodiment according to the present disclosure of an orthopedic cutting guide apparatus **100** comprising a cutting block **102**. As shown, cutting block **102** may be a monolithic piece that can be made from a variety of materials including, without limitation, polymers, plastics, metals, and/or combinations thereof, with an exemplary material being a polymer substrate. A monolithic polymeric cutting block **102** can provide certain advantages over traditional metal surgical instruments, for example, allowing cutting guide apparatus **100** to be lower cost, more sterile, single-use, and more precise. For example, a polymeric cutting block may be discarded after a single use, which obviates the need for a sterilization process generally required for multi-use devices and reduces the degradation effects of multiple uses. As shown, cutting block **102** comprises opposing proximal and distal surfaces **302**, **304**, where proximal surface **302** is configured to engage with the distal end of a femur **104** and distal surface **304** is configured to engage with a cutting instrument. Although the present disclosure and figures focus on application of cutting guide apparatus **100** to a femur for use during knee arthroplasty, it is understood that other embodiments of the present disclosure may apply to other medical procedures and parts of the body such as foot and ankle and/or hand and wrist.

As shown, cutting block **102** further comprises opposing anterior and posterior surfaces **202**, **204** that correspond to the anterior and posterior sides of femur **104** and are substantially orthogonal with proximal and distal surfaces **302**, **304**. Further, cutting block **102** may comprise opposing medial and lateral surfaces **206**, **208** that correspond to the medial and lateral sides of femur **104**, are adjacent to anterior and posterior surfaces **202**, **204**, and are substantially orthogonal with proximal and distal surfaces **302**, **304**. As shown in FIGS. **1-4**, femur **104** is a left femur, so the terms "medial" and "lateral" are made in reference to a left femur. The selection of the terms "medial" and "lateral" as referring to a left femur is made for convenience purposes only, and it is understood that cutting block **102** may be used to prepare a right femur as well, such that the "medial" side of cutting block **102**, as referenced herein, would align with the lateral side of the right femur, and the "lateral" side of the cutting block would align with the medial side of the right femur.

FIG. **2** shows cutting block **102** further comprising first and second slots **210**, **212** that traverse substantially orthogonally through proximal and distal surfaces **302**, **304**, with first slot **210** positioned in an anterior portion of cutting block **102** and second slot **212** in a posterior portion of cutting block **102**. Additionally, FIG. **2** shows cutting block **102** comprising third and fourth slots **214**, **216** positioned between first and second slots **210**, **212** and traversing diagonally through proximal and distal surfaces **302**, **304**. As shown, third and fourth slots **214**, **216** may intersect between proximal and distal surfaces **302**, **304**. In certain embodiments, first, second, third, and fourth slots **210**, **212**, **214**, **216** may horizontally extend substantially the entire width between medial and lateral surfaces **206**, **208**. As used herein, the term "horizontal" is defined with reference to the medial/lateral direction of cutting guide apparatus **100** when secured to the distal end of femur **104**.

FIG. **2** also shows cutting block **102** comprising first, second, and third pinholes **218**, **220**, **222** that traverse through proximal and distal surfaces **302**, **304**, where first pinhole **218** is closest to medial surface **206**, second pinhole **220** is closest to lateral surface **208**, and third pinhole **222** is between—and in some embodiments centered between—first pinhole **218** and second pinhole **220**. In certain embodiments, first, second, and third pinholes **218**, **220**, **222** may traverse through proximal and distal surfaces **302**, **304** substantially orthogonally, while in other embodiments, first, second, and third pinholes **218**, **220**, **222** may traverse through proximal and distal surfaces **302**, **304** at an oblique angle. Although the embodiment shown in FIG. **2** has three pinholes, it is understood that other embodiments may comprise different numbers of pinholes such as two pinholes, four pinholes, five pinholes, or any other reasonable number of pinholes.

As shown in FIG. **5**, cutting guide apparatus **100** may further comprise first, second, and third guide inserts **502**, **504**, **506**, where first guide insert **502** is positioned within first slot **210**, second guide insert **504** is positioned within second slot **212**, and third guide insert **506** is positioned within third and fourth slots **214**, **216** nearer distal surface **304** than proximal surface **302**. First, second, and third guide inserts **502**, **504**, **506** can be made from a variety of materials including, without limitation, polymers, plastics, metals, and/or combinations thereof, with an exemplary material being a metal or metal alloy (e.g., steel) to interact with surgical cutting instruments such as a sagittal saw. Further, first, second, and third guide inserts **502**, **504**, **506** may be insert molded to be fixed within their respective first, second, third, and/or fourth slot **210**, **212**, **214**, **216**. First, second, and third guide inserts **502**, **504**, **506** may be produced in a variety of ways, for example, 3D printed or fabricated from sheet-metal. Although the embodiment shown in FIG. **5** has three guide inserts, it is understood that other embodiments may comprise different numbers of slots and guide inserts. For example, an alternative embodiment not shown may comprise one slot and guide insert in the center of cutting guide **100** where guide insert **506** is shown in FIG. **5**. Any number of desired slots and guide inserts may be used.

FIG. **5** also shows a plurality of pins that are configured to pass through first, second, and/or third pinholes **218**, **220**, **222** and secure cutting guide apparatus **100** to the distal end of femur **104**. Although FIG. **5** only shows two pins **508**, **510** passing through first and second pinholes **218**, **220**, it is understood that other embodiments may comprise additional pins, for example, a third pin configured to pass through third pinhole **222**. The plurality of pins can be made from a variety of materials including, without limitation, polymers, plastics, metals, and/or combinations thereof, with an exemplary material being a metal or metal alloy (e.g., steel) to ensure a secure connection between cutting guide apparatus **100** and the distal end of femur **104**.

In certain embodiments, the only metal parts of cutting guide apparatus **100** are the guide inserts and pins, which allows cutting guide apparatus **100** to be discarded or recycled after a single use, offering benefits over traditional cutting guides such as providing a more cost-effective, precise, and sterile surgical procedure. Embodiments of the present disclosure are more cost-effective because a non-metal cutting block **102** significantly reduces the materials cost of producing cutting guide apparatus **100**, where metal parts are generally more costly than non-metal parts, and reducing the amount of metal therefore reduces the overall cost of the cutting guide apparatus. Additionally, embodiments of the present disclosure are more precise because they can be discarded after a single use, which means that they are not susceptible to the wear and tear of recurring procedures, nor do they inflict as much damage to the surgical cutting instrument or need to be recalibrated after each procedure. Further, embodiments of the present disclosure are more sterile because they are only used for one patient, reducing the chance of contamination from prior procedures. Traditional cutting guides need to be sterilized after each use, which not only increases the risk of contamination, but also requires time (up to 5-6 hours) and other resources to be expended on the sterilization process. This may further reduce the number of procedures that a single hospital or practice can perform in a day where the number of available cutting guides are limited (in some instances, to only one due to the high cost of metal cutting guides) and a physician needs to wait until the cutting guides are sterilized before performing subsequent procedures.

Referring now to FIG. **6**, first guide insert **502** comprises a first slit **602**, second guide insert **504** comprises a second slit **604**, and third guide insert comprises third and fourth slits **606**, **608**. FIG. **6** shows, in broken line, the interior configuration and location of first, second, third, and fourth slits **602**, **604**, **606**, **608**. These slits can be sized to sufficiently accommodate a surgical cutting instrument such as a sagittal saw and formed to provide desired angles and locations for the cuts. In certain embodiments, different guide inserts could be insert molded into the same cutting block such that one cutting block **102** could support numerous different cutting configurations. This is advantageous over traditional cutting guides that do not have guide inserts molded into a cutting block because it allows for one universal cutting block to be versatile and adaptable to different surgical systems and procedures.

FIG. **7** shows, in broken line, the direction of various cuts made to femur **104** through first, second, third, and fourth slits **602**, **604**, **606**, **608**. As shown, first slit **602** is configured to allow for a planar anterior cut **704** (i.e., a cut configured to closely match the geometry of an implant and generally made substantially perpendicular to the anterior surface plane of the anterior portion of cutting guide apparatus **100**) on the distal end of femur **104** by a surgical cutting instrument. Second slit **604** is configured to allow for a planar posterior cut **706** (i.e., a cut configured to closely match the geometry of an implant and generally made substantially perpendicular to the posterior surface plane of the posterior portion of cutting guide apparatus **100**) on the distal end of femur **104** by a surgical cutting instrument. A person of skill in the art would understand that while cuts may be intended to be perpendicular or at another specified angle, in practice, these cuts may vary acceptably from these angles given a particular tolerance level. Third slit **606** is configured to allow for a chamfered posterior cut **708** on the distal end of femur **104** by a surgical cutting instrument. Fourth slit **608** is configured to allow for a chamfered anterior cut **710** on the distal end of femur **104** by a surgical cutting instrument. FIG. **7** also shows that third and fourth slots **214**, **216** may intersect along a midline **702** between anterior surface **202** and posterior surface **204**.

FIGS. **8-10** show another embodiment of a cutting guide **800** according to the present disclosure comprising a plurality of adjustable guide bars **804**, **806**, **808**, **810** mounted on a base **802**. Guide bars **804**, **806**, **808**, **810** and base **802** may be made from a variety of materials such as a polymer (e.g., plastics) or metal (e.g., steel), with one suitable material being polymer. Each guide bar may comprise at least one slot **912**, **914**, **916**, **918**. In the embodiment shown in FIG. **9**, each guide bar comprises two slots, one on either side of base **802**. A plurality of guide inserts **1002**, **1004**, **1006**, **1008** may be positioned within each slot **912**, **914**, **916**, **918**. Guide inserts **1002**, **1004**, **1006**, **1008** may be made from a variety of materials, with one suitable material being metal, and may also be insert molded or press-fit into slots **912**, **914**, **916**, **918**.

A guide key **820** may be applied to guide bars **804**, **806**, **808**, **810** to fix the guide bars in place along base **820**. Without guide key **820**, guide bars **804**, **806**, **808**, **810** can slide along base **820**, which allows for adjustability of the guide bars until they are locked into place by guide key **820**. Guide key **820** maintains the spatial relationship between guide bars **804**, **806**, **808**, **810** along base **802**. Different guide keys **820** can be interchanged and can allow for different spacing between guide bars **804**, **806**, **808**, **810** such that cutting guide **800** can be applied to various sizes and types of bones. In some embodiments, guide bars **804**, **806**, **808**, **810** may engage with each other. Base **802** may comprise a screw thread **902** at one end or throughout to allow a cap **904** to attach at the top of base **802** above the top guide bar **804**, which in connection with guide key **820**, further locks guide bars **804**, **806**, **808**, **810** in place. Although base **802**, guide key **820**, screw thread **902**, and cap **904** are shown in the center of cutting guide **800**, it is understood that other locations are possible, such as at the medial or lateral end of cutting guide **800** or at any other reasonable location along cutting guide **800**. In some embodiments, base **802**, guide key **820**, screw thread **902**, and cap **904** may be replaced with two of each element that are positioned at the medial and lateral outer edges of guide bars **804**, **806**, **808**, **810**. Examples of these different embodiments are shown in FIGS. **11** and **12**.

As with the embodiments discussed above, the cutting guide **800** can be applied to a bone, such as the distal end of femur **104**, for use in orthopedic surgery (e.g., knee arthroplasty, ankle arthroplasty, and wrist arthroplasty). A first of said guide inserts **1002** may comprise a first slit **1012** configured to allow for a planar anterior cut to bone **104**. A second of said guide inserts **1004** may comprise a second slit **1014** configured to allow for a planar posterior cut to bone **104**. A third of said guide inserts **1006** may comprise a third slit **1014** configured to allow for a chamfered posterior cut to bone **104**. A fourth of said guide inserts **1008** may comprise a fourth slit **1018** configured to allow for a chamfered anterior cut to bone **104**. Additionally, one or more pins **1010** may pass through base **802** via one or more pinholes at various angles for securing cutting guide **800** to bone **104**.

It is understood that embodiments presented herein are meant to be exemplary. Embodiments of the present disclosure can comprise any combination or compatible features shown in the various figures, and these embodiments should not be limited to those expressly illustrated and discussed.

Although the present disclosure has been described in detail with reference to certain configurations thereof, other versions are possible. Therefore, the spirit and scope of the disclosure should not be limited to the versions described above. The foregoing is intended to cover all modifications and alternative constructions falling within the spirit and scope of the disclosure as expressed in the appended claims, wherein no portion of the disclosure is intended, expressly or implicitly, to be dedicated to the public domain if not set forth in the claims.

What is claimed is:

1. An orthopedic cutting guide apparatus, comprising:
- a base wherein a first end of said base comprises a screw thread;
- a cap configured to screw into said screw thread;

- a plurality of polymeric guide bars mounted on said base, wherein each of said guide bars comprises at least one slot;
- a plurality of guide inserts positioned within each of said slots; and
- a guide key configured to fix each of said guide bars along said base such that said guide bars maintain a fixed spatial relationship when said guide key is engaged.

2. The cutting guide apparatus of claim **1**, wherein said guide bars are configured to slide along said base when said guide key is disengaged.

3. The cutting guide apparatus of claim **1**, wherein a first of said guide inserts comprises a first slit configured to allow for a planar anterior cut to a distal end of a bone.

4. The cutting guide apparatus of claim **1**, wherein a second of said guide inserts comprises a second slit configured to allow for a planar posterior cut to a distal end of a bone.

5. The cutting guide apparatus of claim **1**, wherein a third of said guide inserts comprises a third slit configured to allow for a chamfered posterior cut to a distal end of a bone.

6. The cutting guide apparatus of claim **1**, wherein a fourth of said guide inserts comprises a fourth slit configured to allow for a chamfered anterior cut to a distal end of a bone.

7. The cutting guide apparatus of claim **1**, further comprising a pin passing through said base via a pinhole and configured to secure said cutting guide apparatus to a bone.

8. The cutting guide apparatus of claim **1**, wherein said base and guide key are positioned in a center of said cutting guide apparatus.

9. The cutting guide apparatus of claim **1**, wherein said plurality of guide bars are configured to engage with each other.

10. An orthopedic cutting guide apparatus, comprising:
- a plurality of polymeric guide bars, wherein each of said guide bars comprises at least one slot;
- a plurality of guide inserts positioned within each of said slots;
- a first base positioned along a medial edge of said plurality of guide bars;
- a second base positioned along a lateral edge of said plurality of guide bars;
- a first guide key configured to fix each of said guide bars along said first base;
- a second guide key configured to fix each of said guide bars along said second base,
- wherein said guide bars maintain a fixed spatial relationship when said guide key is engaged.

11. The cutting guide apparatus of claim **10**, wherein a first end of said first base comprises a first screw thread and a first end of said second base comprises a second screw thread.

12. The cutting guide apparatus of claim **11**, further comprising a first cap configured to screw into said first screw thread and a second cap configured to screw into said second screw thread.

13. The cutting guide apparatus of claim **10**, wherein said guide bars are configured to slide along said first and second bases when said first and second guide keys are disengaged.

14. The cutting guide apparatus of claim **10**, further comprising one or more pins passing through said first and/or second bases via one or more pinholes and configured to secure said cutting guide apparatus to a bone.

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